

REMARKS

**Status of Claims:**

Claims 1 and 52 have been amended. Claims 24-48 were previously cancelled without prejudice or disclaimer. Claims 1-23 and 49-54 are present for examination. No new matter is added by the present Amendment. Re-examination and reconsideration of the application, as amended are requested.

**Claim Rejections:**

1. Claims 1-11, 14-23 and 49-54 have been rejected under 35 U.S.C. 102 (b) as being anticipated by Barry (U.S. Patent Application No. US2002/0077592 A1) (hereinafter Barry).
2. Claims 12-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Silver (U.S. Patent No. 6,442,413) (hereinafter Silver).
3. Claims 4, 19-23 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Barry.

Each of those rejections is respectfully traversed. Applicant requests reconsideration of the present application in view of the following remarks.

**Applicant's Argument Traversing the Rejections:**

Independent claims 1 as amended recites a method for mitigating restenosis at a trauma site at which a stent is located within the vasculature comprising positioning a catheter adjacent the trauma site; extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and delivering a restenosis mitigating drug to the trauma site through the catheter. Barry neither discloses nor suggests a method having the above-noted features including “positioning a catheter adjacent the trauma site; extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent; and delivering a restenosis mitigating drug to the trauma site through the catheter.”

In the Office Action, the Examiner refers to Barry's element 255 as "extending a sensor through a lumen in the catheter and through the stent. (January 12, 2007 Office Action, pg. 2.) However, referring to Figs. 11 and 13-15 of the Barry reference, a heat sensor element 255 is located on a catheter 230, within the interior of the stent 236 and balloon 235. Barry does not disclose or suggest extending a sensor through a lumen to a position located outside of the catheter and outside of the stent. In addition, Barry does not disclose or suggest extending a sensor through a stent to a position located outside of the catheter and outside of the stent.

Instead, Barry discloses a sensor 255 that is likely permanently fixed to the catheter body at a location to be within the interior of the balloon 235. Barry's sensor 255 is specifically provided for sensing the temperature of inflation fluid in the balloon 235. (Barry, paragraphs 0088 and 0089.) Barry teaches to run conductors 251 through the lumen 38 between the sensor 255 and an external heating source 252. (Barry, paragraph 0088.) However, the sensor 255, itself, must be located within the balloon 235 (as shown in Barry's drawings) to function as described by Barry, to sense the temperature of inflation liquid 234 in the balloon.

To position the sensor 255 within the balloon 235, Barry's sensor would most likely be permanently fixed to the catheter 230 at the balloon location, during manufacture of the catheter. (Barry does not provide details regarding how the sensor 255 is mounted, but the disclosed function of the sensor indicates that the sensor 255 must be fixed in the balloon area of the catheter body.) It would be impractical to extend a sensor 255 through a lumen in a catheter and accurately locate the sensor within the interior of the balloon 235 during a restinosis treatment procedure. Indeed, Barry provides no mechanism for determining how the medical practitioner could possibly know when the sensor 255 is at the proper location within the balloon. That is because Barry does not contemplate, teach or suggest passing a sensor through a lumen in the catheter to a position located outside of the catheter. Instead, because of the need to place the sensor 255 within the balloon, Barry would lead one skilled in the art to install a sensor at a fixed location (a balloon location) on the catheter during manufacture of the catheter. Accordingly, Barry does not anticipate the method of claim 1, which includes "extending a sensor through a lumen in the catheter to a position located outside of the catheter."

In addition, Barry does not disclose or suggest extending a sensor through a stent to a position located outside of the stent. To extend through the stent, as shown in Applicant's Figs. 1 and 2, the sensor 12b enters at the left side of the stent 18 and exits at the right side of the stent 18. In contrast, while Barry's sensor 255 is located *within* the stent 235, Barry's sensor 255 does not extend *through* the stent 255 to a position located outside of the stent. Locating the sensor 255 within the stent 235 is not the same as extending a sensor through a stent to a position located outside of the stent. The term "through" has an ordinary and common meaning that involves the combination of moving in and out, which is different from merely "within" an interior. Also according to page 1230 of Webster's Ninth New Collegiate Dictionary 1983, the term "through" has an ordinary meaning that indicates movement into at one side or point and out at another. To further explain the definition of "through" used in the claim, the amended claim specifically states "extending a sensor through a lumen in the catheter and through the stent to a position located outside of the catheter and outside of the stent. Barry's thermal sensor 255 is located within the stent 235, but does not extend out of the stent 235.

Thus, Barry's thermal sensor 255 does not extend through the stent 235, to a position located outside of the catheter and outside of the stent. Indeed, Barry's thermal sensor 255 could not also extend out (or through) the stent 255, without rendering the sensor inoperative for its disclosed purpose (which is to sense the temperature of fluid in the balloon inside the stent). In that regard, Barry's thermal sensor 255 is not extending through the stent 235 to a position located outside of the catheter and outside of the stent. According, Barry does not anticipate the amended method of claim 1, which further includes "extending a sensor ... through the stent to a position outside of the catheter and outside of stent."

According to the Federal Circuit "[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration.<sup>1</sup> The prior art reference must disclose each element of the claimed invention "arranged as in the claim."<sup>2</sup> Because the Barry reference does not disclose each element of claim 1, the Barry reference does not anticipate the method of claim 1. Therefore the Examiner has failed establish anticipation under 35 U.S.C. 102(b).

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<sup>1</sup> W.L. Gore & Assocs. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983)

<sup>2</sup> Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983))

The rejection of claim 1 is therefore, respectfully traversed. Claims 2--23 and 49-51 are dependent on claim 1 and are believed to be allowable over the Barry reference at least for reasons as discussed above with respect to claim 1. While the Examiner combined the Silver patent with the Barry reference to form the rejection of claims 12 and 13, the Silver patent does not address the above-noted distinctions over the Barry reference.

The rejection of claim 52 is respectfully traversed for reasons similar to those discussed above with respect to claim 1. In particular, claim 52 recites a method that includes, among other features, "extending a sensor through the catheter and through the stent to a position located outside of the catheter and outside of the stent. As described above with respect to claim 1, Barry neither describes nor suggests extending a sensor through a catheter to a position located outside of the catheter. Instead, Barry's thermal sensor 255 seems to be fixed to the catheter 230 at a location inside the balloon 235. In addition, Barry neither describes nor suggests extending a sensor through a stent to a position located outside of the stent. Instead, Barry's thermal sensor 255 is located inside of the stent and does not extend out of the stent.

The rejection of claim 52 is therefore, respectfully traversed. Claims 53 and 54 are dependent on claim 52 and are believed to be allowable over the Barry reference at least for reasons as discussed above with respect to claim 52.

Due to the aforementioned differences between Barry and the current invention, the Examiner has failed to meet the legal standard for showing anticipation under 35 U.S.C. 102 (b) or obviousness under 35 U.S.C. 103(a) for claims 1-23 and 49-54.

**Conclusion:**

Applicant respectfully submits that in view of the foregoing remarks the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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